DR.EL CLAIR TOOTH- silicon dioxide, sodium monofluorophosphate paste, dentifrice
Dr. EL CO., LTD.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SILICON DIOXIDE, SODIUM MONOFLUOROPHOSPHATE

For dental care

Keep out of reach of children

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician

Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)

Children under 2 years: Ask a dentist or physician

(1) Contains 290ppm of fluoride.

(2) Do not swallow and rinse mouth thoroughly after use

(3) If you experience any problems with your gums or mouth during use,

discontinue use and consult your doctor.

(4) For children under 6 years of age, use small amounts of toothpaste. And use it under the supervision of a guardian to avoid sucking or swallowing.

(5) Consult a physician or dentist immediately if a child under 6 years old has swallowed large quantities.

(6) Keep out of the reach of children under 6 years of age.

D-Sorbitol Solution, Water, Concentrated Glycerin, Xantangum, Sodium Cocoyl Glutamate, Raspberry Flavor, Black Current Flavor, Xylitol, Chitosan, Rosemary Extract, Matricaria Extract, Eucalyptus Extract, Sage Extract, Aloe Extract, Green Tea Extract, Ascorbic Acid, Tocopherol Acetate

For dental use only

DR.EL CLAIR TOOTH

silicon dioxide, sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72440-104
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.22 g in 100 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	8 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72440-104-01	60 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2019	

Labeler - Dr. EL CO., LTD. (694771074)

Registrant - Dr. EL CO., LTD. (694771074)

Establishment

Name	Address	ID/FEI	Business Operations
DONG IL PHARMS CO.,LTD		557810721	manufacture(72440-104)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. EL CO., LTD.		694771074	label(72440-104)

Revised: 9/2019 Dr. EL CO., LTD.